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GUARDANT HEALTH, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.

Plaintiff and
Counterclaim-Defendant,

vs.

NATERA, INC.

Defendant and
Counterclaim-Plaintiff.

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Case No. 3:21-cv-04062-EMC

**GUARDANT'S TRIAL BRIEF TO
PRECLUDE FURTHER EVIDENCE
REGARDING MOLDX DELAY OF
MEDICARE COVERAGE AND
MISLEADING THE JURY THAT
GUARDANT'S COMMUNICATIONS
WITH MOLDX CONSTITUTE
"ADVERTISING" IN VIOLATION OF
ORDER ON NATERA MIL NO. 2 (DKT.
509 / DKT. 572)**

Next Trial Date: November 13, 2024

Guardant respectfully asks the Court to preclude Natera from offering further evidence regarding MolDX's delay of Medicare coverage for Reveal, or from misleading the jury into believing that Guardant's communications with MolDX constitute "advertising," in violation of this Court's Order on Natera's MIL No. 2, Dkt. 509, public redacted Dkt. 572.

I. Natera has turned MIL No. 2 into a sword and a shield

As the very start of Project SOLAR, Natera identified a strategy of communicating with MolDX about "the GH test" as key to its "innovative ideas to blunt Guardant." TX 097 (Jan. 22, 2021). Following Natera's concerted (though behind-the-scenes) efforts, e.g., TX-225, MolDX delayed extending coverage for Reveal by about a year. In its second motion in *limine*, however, Natera contended that evidence of its efforts to interfere with MolDX's coverage approval for Reveal should be excluded from trial.

In addressing MIL No. 2, the Court held that to constitute "advertising," "[t]he Lanham Act requires that the communication be directed at or received by consumers." Dkt. 572 at 5. Here, "Natera's letters to MolDX"—like Guardant's own communications with MolDX—"were not disseminated to consumers directly but sent privately to MolDX." *Id.* Accordingly, the Court held that Natera's communications with MolDX were not "advertising." *Id.*

Because Natera's false statements to MolDX did not constitute "advertising," they were not actionable as false advertising under the Lanham Act. Dkt. 572 at 6-7. And for this reason, for its lost profits claim, Guardant will not be allowed to show the jury that MolDX delayed Medicare approval for Reveal. *Id.* at 7. Moreover, the Court concluded that "determining whether MolDX would not have delayed approval but for the statements made by Natera . . . would involve establishing the thoughts and motivations of MolDX officials, examination of all the materials considered by MolDX, and would thus entail a trial within a trial to prove causation." *Id.* at 8. Thus, as Natera had asked, evidence about the reasons for MolDX's delay of Medicare coverage are expressly excluded from trial. *Id.* at 9 ("Evidence regarding the outcome of statements made by Natera to MolDX ***and the decision to delay coverage is to be excluded at trial.***") (emphasis added).

1 On the other hand, the Court expressly did not exclude *all* evidence regarding Natera's
2 statements to MolDX. This is so because:

3 the statements made [by Natera] to MolDX do inform Natera's state of mind when
4 it embarked upon its advertising against Guardant's product, Reveal. Specifically,
5 to the extent that Natera made unfounded statements to MolDX regarding issues
6 with Reveal, this tends to show Natera's intent to disparage Guardant/Reveal,
7 including a motivation to undermine Reveal in its advertising statements as well.

8 Dkt. 572 at 8. As the Court explained, "Natera's state of mind is relevant in a few ways. If Guardant
9 establishes that Natera intended to deceive consumers, there is a presumption that consumers were
10 in fact deceived," and "punitive damages may be appropriate if Guardant establishes that Natera
11 acted maliciously." *Id.* (citation omitted). Similarly, Guardant is allowed to use Natera's
12 communications with MolDX to rebut Natera's "narrative" "that in challenging Reveal, it was
13 motivated by altruism and a desire to save patients and educate oncologists." *Id.* at 8-9 (observing:
14 "Natera's statements to MolDX may be probative in this regard."); *accord*, Dkt. 611, public
15 redacted Dkt. 625-3 at 11 (bellwether rulings, rejecting Natera challenges to TX-225 and similar
16 documents, but noting: "Documents that speak to the impact of statements to MolDx will not be
17 admissible for that purpose.")

18 In sum, "[b]ecause the statements to MolDX are not actionable under the Lanham Act, but
19 are relevant to establishing Natera's state of mind," the Court will not allow "[e]vidence regarding
20 the outcome of statements made by Natera to MolDX and the decision to delay coverage," but will
21 allow "evidence regarding statements made to MolDX by Natera for the purpose of showing
22 Natera's state of mind at the time it launched its advertising campaign." Dkt. 572 at 9.

23 Natera has aggressively tested this distinction between the uses for which MolDX evidence
24 may be used, wielding the Court's MIL No. 2 MolDX ruling as both sword and shield. In his
25 opening on behalf of Natera, Natera's counsel affirmatively declared that Natera is *not* responsible
26 for MolDX's delay of Medicare coverage—to which Guardant's own opening had not alluded—
27 and instead claimed MolDX's decision was solely due to a "data gap":

28 You will hear also that when it comes to Guardant's efforts to obtain Medicare
coverage, there was another important thing that will come out in this trial. And the
evidence will show that although Guardant obtained some limited Medicare
coverage for Reveal, they did not receive Medicare coverage for use of Reveal for

recurrence monitoring. That's surveillance where you take it every few months over and over, over a period of years, to see if the cancer has come back. They have not received Medicare in the surveillance setting.

Guardant's counsel tried to make it sound like Natera interfered with Guardant obtaining Medicare coverage for Reveal, ***but the evidence will show that it was because of the deficiencies in Guardant's own data that it didn't get Medicare coverage for recurrence monitoring.***

Guardant, again, had a data gap. That's not Natera's word. That's their word -- term, "data gap." ***And MolDX, which you'll hear about, that's the group that makes the decision about Medicare coverage for these tests, they saw the same data gap.*** And the people at MolDX are highly qualified experts.

Trial Tr.268:18-269:11 (emphasis added). In this same argument to the jury, Natera's counsel represented that "when it was beneficial for Guardant to compare the studies side by side, they did it. But they now want you to believe that it was somehow wrong for Natera to do the same thing." *Id.* at 268:14-17. But Guardant's comparisons between studies to MolDX were not only *required* by the Local Coverage Decision (LCD), but per this Court's ruling, ***are not advertising.***

Guardant raised these concerns following Natera's opening, and the Court concluded "that the opening statements, because they are not evidence, does not open the door at this point." Trial Tr. at 317:18-20. The Court cautioned Natera, however: "If you introduce any kind of evidence that suggests that there was a data gap and that was the reason, that would open the door." *Id.* at 317:20-22; *see also id.* at 317:24-318:1 ("it's a warning that if you to do get into that in terms of the evidence, we may be talking about a different ballgame"). And when Natera's counsel pushed back on this warning, *id.* at 318:2-9, the Court again cautioned Natera: "you don't need to get into why it [Reveal] wasn't approved for all purposes. That's not relevant. I'm limiting this to the very narrow purpose that I had allowed this in." *Id.* at 318:10-12.

Notwithstanding these warnings, Natera spent a significant portion of its cross-examination of Dr. Odegaard on Guardant's communications with MolDX. *See* Trial Tr. at 369:22-386:7. Natera thus elicited testimony regarding the quality of data required by MolDX for approval:

- Q. Okay. Now, you agree with me that MolDX approval, just because you have a test going through that process, is not guaranteed?
- A. Agreed.
- Q. Okay. There's an application process, and you have to actually submit some clinical and analytical validation data?
- A. That's correct.

1 Q. And it has to be published, peer-reviewed data; right?

A. The clinical data, yes.

2 Q. The clinical data.

3 *Id.* at 370:-16. Natera asked about the scope of coverage potentially allowed under the LCD:

4 Q. Now, in that decision, that LCD that you were floating around, Medicare
5 defined two scenarios in which MRD testing for CRC would be covered;
right?

A. That's correct.

6 Q. Adjuvant on the one hand --

A. Yes.

7 Q. -- correct?

And surveillance setting on the other?

8 A. Correct.

9 Q. And "surveillance" refers to recurrence monitoring where you look at
patients over months or years?

10 A. Correct. Yeah.

11 *Id.* at 372:4-18. And Natera asked about the timing of Guardant's application for coverage:

12 Q. And then in December of 2020, Guardant applied for the same Medicare
coverage under the Signatera LCD?

13 A. Correct.

14 *Id.* at 374:21-23; *see also id.* at 375:20-22 (timing of submission).

15 Natera's questioning also sought to confuse the jury as to the distinction between
16 Guardant's communications with MolDX—which again ***are not advertising***—and the false
17 advertising counterclaims raised by Natera. E.g., Trial Tr. at 377:13-25 (technical error in specific
18 reference to “blinding” in MolDX Technical Assessment which is not repeated in any Guardant
19 advertising). Natera also sought to liken its own comparative advertising with Guardant's non-
20 advertising efforts to satisfy MolDX. *Id.* at 383:9-386:7 (testimony about cross-study comparisons
21 made by Guardant to MolDX). Guardant again raised objections, *id.* at 419:10-25, but the Court
22 again concluded that “[a]t this point, the door has not been opened.” *Id.* at 420:13-14.

23 Undeterred, in today's examination of Dr. Eltoukhy, Natera's counsel twice tried to
24 question Guardant's CEO about MolDX's decision-making. While the Court sustained Guardant's
25 objections, it is plain Natera will continue—through improper questions and documents—to
26 convince the jury that MolDX had good reasons to disapprove of Reveal. Thus, in its exhibit
27 disclosures earlier today for Mr. Mark McCoy, a Guardant witness to be presented by Natera early
28

1 in its case-in-chief, Natera telegraphs it plan to not just open the door, but break it down entirely.
2 Its exhibits for Mr. McCoy focus almost exclusively on Guardant’s communications with and
3 about MolDX, including TX-610, a May 18, 2021 email from MolDX to Guardant, apologizing
4 “that it’s taking longer than anticipated,,” but “[h]oping to have something back to you soon.” This
5 exhibit goes directly to the delay in Medicare coverage that Guardant is not allowed to discuss.
6 Natera’s proposed exhibits also include TX-611, a June 1, 2021 communication with MolDX (and
7 thus well after Natera implemented the MolDX-arm of its SOLAR strategy), responding to
8 MolDX’s technical question about Reveal. This email has nothing to do with Guardant’s or
9 Natera’s advertising, but instead, at most, goes to issues of delay.

10 In this same vein, TX-612 is a June 29, 2021 internal Guardant communication from Mr.
11 McCoy, expressing frustration with MolDX’s delay, and speculating as to MolDX’s state of mind.
12 This directly implicates the Court’s reasoning for excluding such evidence, as it invites a mini-
13 trial as to MolDX’s reasons for delaying coverage. Dkt. 572 at 8 (“This would involve establishing
14 the thoughts and motivations of MolDX officials, examination of all the materials considered by
15 MolDX, and would thus entail a trial within a trial to prove causation”). Similarly, TX-613 is an
16 internal Guardant communication discussing whether to send GNE bakeoff data to MolDX—
17 which Guardant ultimately did not do, in part because of GNE’s concerns over the instant lawsuit.

18 The exhibits Natera intends to use with Mr. McCoy—and the testimony it will try and elicit
19 from him—are not relevant to Natera’s state of mind or the advertising claims at issue in this case.
20 Instead, Natera’s intended use goes to its efforts to convince the jury that, as Natera’s counsel
21 argued at opening, “the people at MolDX, who “are highly qualified experts,” in fact “saw that
22 despite the Guardant -- what it was claiming in its ads, Guardant doesn't have the data supporting
23 the sensitivity and specificity of Reveal in the recurrence monitoring setting.” Trial Tr. at 269:11-
24 15.

25 Of course, none of that is true; MolDX reviews data, not advertising. But pursuant to this
26 Court’s Order, Guardant cannot and will not present an appropriate counter-narrative to the jury.
27 Pursuant to that same Order, as well as fundamental principles of fairness, Natera must not be
28

1 allowed to mislead the jury into believing that Reveal’s coverage was delayed because of a “data
2 gap” or any other issues with the assay. Nor should Natera be allowed to continue to mislead the
3 jury into believing that Guardant’s communications with MolDX are “advertising.”

4 Absent a firm ruling on this issue, Guardant would be irreparably prejudiced. Guardant
5 already has put on much of its affirmative case and many of its expected witnesses. Guardant did
6 so in compliance with this Court’s decision on MIL No. 2. If Natera is allowed to continue
7 violating that decision, Guardant would be unable to respond fully and effectively, as many of its
8 key witnesses on those issues have already testified.

9 Respectfully submitted,

10
11 Dated: November 12, 2024

**ALLEN OVERY SHEARMAN
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing document has been served on November 12, 2024, to the counsel of record via email to qe-natera-guardant@quinnemanuel.com.

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